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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/905,247      | 07/13/2001  | Yi-Bao Ke            | 04399/000J615-US0   | 4883             |

7590 05/03/2006

DARBY & DARBY P.C.  
27th Flr.  
805 Third Avenue  
New York, NY 10022

EXAMINER

DESAI, ANAND U

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1653

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                   |                           |  |
|------------------------------|-----------------------------------|---------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/905,247     | Applicant(s)<br>KE ET AL. |  |
|                              | Examiner<br>Anand U. Desai, Ph.D. | Art Unit<br>1653          |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,9-11 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 9-11, and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. <u>20060501</u> .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20050812</u> .  | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on August 12, 2006 has been entered.

### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The priority date is August 2, 2000.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on August 12, 2005 is being considered by the examiner. The Ke et al. reference (document CF) is crossed out, because it was previously cited on the IDS filed September 26, 2001.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. In claim 1, it is unclear if the modification of at least one amino acid residue in regions 174 to 180, 203 to 266, and 230 to 244 are in each region or in one particular region?

*Claim Objections*

7. Claims 9-11, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art of Record

He et al. (IDS document CB) disclose the modification of trichosanthin at position glutamine 219 with cysteine to reduce the immunogenicity. The modified trichosanthin is conjugated with polyethylene glycol to increase the plasma half-life using the modified cysteine residue. He et al. does not disclose the modification of glutamine with lysine or glycine residues.

*Conclusion*

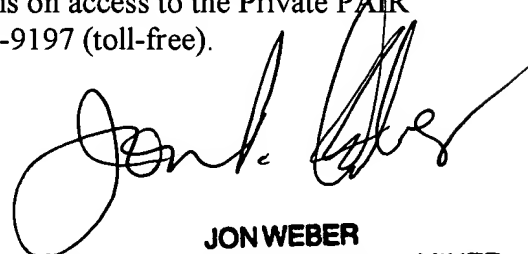
8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 1, 2006



**JON WEBER**  
SUPERVISORY PATENT EXAMINER

## DETAILED ACTION

### DRAFT PROPOSED EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment **was not** approved or given by Applicant's representative.

#### Examiners Amendment to the Claims:

1. (Currently Amended) A mutant trichosanthin (MTCS) protein, comprising the amino acid sequence as set forth in SEQ ID NO:8, with the modification of at least one amino acid residue in each of the following three regions: amino acid residues 174 to 180, 203 to 226, and 230 to 244, wherein the modification is selected from:

(a) arginine at position 174, lysine at position 177, arginine at position 222, and arginine at position 243 are each independently replaced with glutamic acid, aspartic acid, or glycine;

(b) aspartic acid at position 176, asparagine at position 205, asparagine at position 206, glutamine at position 208, glutamic acid at position 210, asparagine at position 217, glutamine at position 219, asparagine at position 220, glutamine at position 221, asparagine at position 236, asparagine at position 242, and asparagine at position 244 are each independently replaced with lysine or glycine;

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(c) threonine at position 178, serine at position 203, threonine at position 204, serine at position 211, threonine at position 224, threonine at position 226, threonine at position 234, and serine at position 235 are each independently replaced with glycine or alanine; and

(d) valine at position 175, phenylalanine at position 179, leucine at position 180, glycine at position 207, phenylalanine at position 209, proline at position 212, valine at position 213, valine at position 214, valine at position 215, valine at position 223, isoleucine at position 216, isoleucine at position 225, alanine at position 218, alanine at position 230, alanine at position 238, glycine at position 231, valine at position 232, valine at position 233, isoleucine at position 237, leucine at position 239, and leucine at position 240 are each independently deleted.

*Allowable Subject Matter*

2. Claim 1, 9-11, and 16 are allowed.

3. The following is an examiner's statement of reasons for allowance:

The prior art does not describe a mutant trichosanthin protein comprising SEQ ID NO: 8, with at least one amino acid modification in each of the following three regions, 174 to 180, 203 to 226, and 230 to 244, which retains ribosome-inactivating activity.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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May 1, 2006

**DRAFT PROPOSED EXAMINER'S AMENDMENT**